

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Currently Amended) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as multiple-powdered active ingredients comprising distinct mean particle sizes, said method comprising:

(a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes;

[[(a)]](b) mixing said active ingredients and at least one chosen excipient so as to obtain a powdered mixture;

[[(b)]](c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;

[[(c)]](d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules; and

[[(d)]](e) forming said granules into unitary dosage forms.

2. (Currently Amended) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as multiple-powdered active ingredients comprising distinct mean particle sizes, said method comprising:

(a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes;

[[(a)]](b) mixing said active ingredients and at least one chosen excipient so as to obtain a powdered mixture;

[[(b)]](c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;

- [[(c)]] (d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules;
- [[(d)]] (e) mixing said granules with at least one chosen excipient so as to obtain a granular mixture; and
- [[(e)]] (f) forming said granular mixture into unitary dosage forms.
3. (Currently Amended) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as ~~multiple-powdered~~ active ingredients ~~comprising distinct mean particle sizes~~, said method comprising:
- (a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes;
- [[(a)]] (b) mixing said active ingredients so as to obtain a powdered mixture;
- [[(b)]] (c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;
- [[(c)]] (d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules;
- [[(d)]] (e) mixing said granules with at least one chosen excipient so as to obtain a granular mixture; and
- [[(e)]] (f) forming said granular mixture into unitary dosage forms.
4. (Currently Amended) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as ~~multiple-powdered~~ active ingredients ~~comprising distinct mean particle sizes~~, said method comprising:
- (a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes;
- [[(a)]] (b) mixing at least one of said active ingredients and at least one excipient so as to obtain a powdered mixture;

- [[(b)]] (c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;
 - [[(c)]] (d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules;
 - [[(d)]] (e) mixing said granules with at least one other active ingredient so as to obtain a granular mixture; and
 - [[(e)]] (f) forming said granular mixture into unitary dosage forms.
5. (Currently Amended) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as multiple-powdered active ingredients comprising distinct mean particle sizes, said method comprising:
- (a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes;
 - [[(a)]] (b) mixing at least one of said active ingredients and at least one excipient so as to obtain a powdered mixture;
 - [[(b)]] (c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;
 - [[(c)]] (d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules;
 - [[(d)]] (e) mixing said granules with at least one other active ingredient and at least one other excipient so as to obtain a granular mixture; and
 - [[(e)]] (f) forming said granular mixture into unitary dosage forms.
6. (Previously Presented) The method of claim 1 wherein the step of forming said granular mixture into unitary dosage forms comprises compressing said granular mixture into a tablet shape.

7. (Previously Presented) The method of claim 6 wherein the tablet shape is provided with a coating.
8. (Previously Presented) The method of claim 7 wherein said coating is an enteric coating.
9. (Previously Presented) The method of claim 1 wherein the step of forming said granular mixture into unitary dosage forms comprises loading said granular mixture into an open capsule and thereafter closing said capsule.
10. (Cancelled).
11. (Previously Presented) The method of claim 1 wherein the active ingredients comprise equal parts of Pyridoxine HCl and Doxylamine Succinate.
12. (Previously Presented) The method of claim 1 wherein the active ingredients consist of equal parts of Pyridoxine HCl and Doxylamine Succinate.